K121144

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SHARP

## 5. 510(k) SUMMARY

SEP 26 2012

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| Submitter: | Sharp Corporation<br>2613-1, Ichinomoto-Cho<br>Tenri, Nara, Japan 632-8567 |
| Contact Person: | Mr. Yoshiro Yamamoto<br>Supervisor<br>Research dept.1 Healthcare Systems Laboratories<br>Corporate Research and Development Group<br>TEL: +81-743-65-2142<br>FAX: +81-743-65-3441<br>email: yamamoto.yoshiro@sharp.co.jp |
| Date Prepared: | *April 11, 2012* |
| Trade Name: | Sharp Electronic Stethoscope Model BM-520 |
| Common Name: | Electronic Stethoscope |
| Classification Name: | Stethoscope, Electronic |
| Product Code: | DQD |
| Classification: | Class II, 21 CFR 870.1875 |
| Predicate Device: | K050159, K041934 3M Littmann Stethoscope, Model 3100<br>K083903 3M Littmann Stethoscope, Model 3200 |
| Device Description: | The *Sharp Electronic Stethoscope Model BM-520* is an electronic stethoscope to auscultate sounds from heart, lung, blood vessels, and other internal organs. It can be used on adults undergoing a physical assessment. The sounds can also be transmitted to an appropriately configured receiving device via Bluetooth® wireless communication. |
| Statement of Intended Use: | The BM-520 Electronic Stethoscope is intended for medical diagnostic purposes only. It may be used for the detection and amplification of sounds from heart, lungs, blood vessels, and other internal organs. It can be used on any person undergoing a physical assessment. |
| Summary of Technological Characteristics: | The *BM-520* operates continuously to provide sounds from heart, lungs, and blood vessels. The sounds detected by the chest piece are output through the ear tips after being amplified and digitally filtered. At the same time, the sounds can be transmitted to an appropriately configured receiving device via Bluetooth® wireless communication. The BM-520 offers two selectable modes, Bell and Diaphragm. Volume is adjustable between 0 and 48 dB. Auto-shutoff feature after 1 minute of inactivity to conserve battery life. |

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Summary of Test Data:

The *Sharp BM-520* was developed and is produced under consideration of all applicable technical standards and internal specifications. The performance of the *BM-520* has been verified in the course of bench testing and software validation testing.

Conclusion:

*Sharp Corporation* considers the *BM-520* to be substantially equivalent to the predicate devices listed above. This conclusion is based on the similarities in primary intended use, principles of operation, functional design, and established medical use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

SEP 26 2012

Sharp Corporation
c/o Ms. Diane Rutherford
Regulatory Engineer
Ken Block Consulting
1201 Richardson Drive, Suite 280
Richardson, TX 75080

Re: K121144
Trade/Device Names: Sharp Electronic Stethoscope, Model BM-520
Regulatory Number: 21 CFR 870.1875
Regulation Name: Electronic Stethoscope
Regulatory Class: Class II (Two)
Product Code: DQD
Dated: August 24, 2012
Received: August 29, 2012

Dear Ms. Rutherford:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

## INDICATIONS FOR USE

510(k) Number: K121149

Device Name: Sharp *Electronic Stethoscope, Model BM-520*

Indications for Use:

*The BM-520 Electronic Stethoscope is intended for medical diagnostic purposes only. It may be used for the detection and amplification of sounds from heart, lungs, blood vessels, and other internal organs. It can be used on any person undergoing a physical assessment.*

Prescription Use ____X____ AND/OR Over-the-Counter Use _____
(21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDHR, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K121149